DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 31, 2015

Davol Incorporated, Subsidiary of C. R. Bard Incorporated
Mr. Steve Keenan
Regulatory Affairs Engineer
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K142818
Trade/Device Name: Phasix™ Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OOD
Dated: February 18, 2015
Received: February 19, 2015

Dear Mr. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142818

Device Name
Phasix™ Mesh

Indications for Use *(Describe)*

The Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92

I. Submitter

Company Name:	Davol, Inc., Subsidiary of C. R. Bard, Inc.
Company Address:	100 Crossings Boulevard Warwick, RI 02886
Telephone:	(401) 825-8499
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Submitter's Name:	Steve Keenan Regulatory Affairs Engineer
Email:	steve.keenan@crbard.com
Date Prepared:	September 26, 2014

II. Device

Trade Name:	Phasix™ Mesh
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Film (21 CFR § 878.3300)
Regulatory Class:	Class II
Product Code:	OOD

III. Predicate Device

- TephaFLEX® Mesh
  - K113723 (Tepha, Inc.), FDA cleared on February 15, 2012
  - K111946 (Tepha Inc.), FDA cleared on September 26, 2011
  - K070894 (Tepha Inc.), FDA cleared on April 13, 2007

IV. Device Description

The proposed Phasix™ Mesh utilizes a fully resorbable poly-4-hydroxybutyrate (P4HB) polymer material. The P4HB is produced from a naturally occurring monomer and is processed into monofilament fiber then knitted into a surgical mesh. The Phasix™ Mesh is packaged individually as a sterile, single flat mesh available in several rectangular sizes and one small circle. Phasix™ Mesh provides immediate short term support and provides a scaffold that enables tissue in-growth over time while the mesh predictably and gradually degrades via hydrolysis and a hydrolytic enzymatic digestive process. Preclinical implantation studies indicate that Phasix™ Mesh retains approximately 70% of its strength at 12 weeks. Absorption of the mesh material will be essentially complete within 12 to 18 months.

V. Indications for Use

Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

VI. Comparison of Technological Characteristics with the Predicate Device

The proposed Phasix™ Mesh has the same materials and design as the predicate TephaFLEX® Mesh. The proposed and predicate devices are constructed of the same P4HB monofilament knitted to create a mesh with the same weave characteristics. Both devices have the same indications for use statement and are intended for use in the reconstruction and repair of soft tissue deficiencies where weakness exists such as hernia repair. In addition, the proposed device and the predicate device are packaged in the same materials including a DuPont™ Tyvek® envelop and foil pouch that undergo the same ethylene oxide sterilization method. Where minor process technology differences

exist, or manufacturing facilities have been changed between the proposed device and the predicate device, performance testing demonstrates that these differences do not adversely affect the safety and effectiveness of the proposed device.

VII. Performance Data:

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility Testing

The proposed Phasix™ Mesh uses the same P4HB monofilament as the predicate TephaFLEX® Mesh. Therefore, biocompatibility testing previously conducted for the predicate TephaFLEX® Mesh was leveraged in support of the proposed device. Additional cytotoxicity testing was performed on the proposed device to confirm that the manufacturing facility changes and minor process modifications had no impact on the device. The cytotoxicity results met acceptance criteria with passing results. The biocompatibility evaluation for the TephaFLEX® Mesh was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process" as recognized by FDA. The proposed Phasix™ Mesh and predicate TephaFLEX® Mesh are considered tissue/bone contacting permanent implants. Therefore, the following tests were leveraged from the predicate device in support of this premarket notification:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity
- Genotoxicity

- Chronic Toxicity
- Implantation
- Haemocompatibility

All biocompatibility data leveraged from the predicate TephaFLEX® Mesh and the additional cytotoxicity testing on proposed Phasix™ Mesh met acceptance criteria.

Electrical safety and electromagnetic compatibility (EMC)

There are no electrical or metal components in the Phasix™ Mesh; therefore the proposed device does not require EMC and Electrical Safety evaluation.

Software Verification and Validation Testing

The proposed Phasix™ Mesh does not contain software.

Bench Testing

Bench testing was performed to compare the proposed Phasix™ Mesh to the predicate TephaFLEX® Mesh. In accordance with FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh" published March 2, 1999, the following physical and performance characteristics were evaluated:

- Mesh weave characteristics
- Mesh pore size
- Mesh density
- Mesh thickness
- Device stiffness
- Burst strength

- Tear resistance
- Suture pullout strength.

Animal Studies

In vivo studies were performed to characterize the mechanical strength and resorption profile of the P4HB monofilament mesh and were originally provided in support of the predicate TephaFLEX® Mesh via K113723. Since the proposed Phasix™ Mesh is constructed of the same P4HB monofilament knitted into a mesh with the same weave characteristics as the predicate TephaFLEX® Mesh, these resorption studies were adopted and provided in support of the Phasix™ Mesh.

Clinical Study

No clinical study was required in support of the Phasix™ Mesh.

VIII. Conclusion:

All test results provided in this submission support and demonstrate that the proposed Phasix™ Mesh is substantially equivalent to the cited TephaFLEX® Mesh predicate.